K040427

MAY - 3 2004

Rev.: April 23, 2004

510(k) SUMMARY

APPLICANT: Medical Device Technologies, Inc.
3600 SW 47th Avenue
Gainesville, FL 32608

CONTACT: Karl Swartz
Quality Assurance Manager

TELEPHONE: (352)338-0440
fax (352)338-0662

TRADE NAMES: Fibrex™ Catheter Patency Device

COMMON NAME: Intravascular therapeutic catheter

CLASSIFICATION NAME: Catheter,intravascular,therapeutic,short, Regulation Number 880.5200

PRODUCT CODE: FOZ

PANEL: General Hospital

SUBSTANTIAL EQUIVALENCE:

Company Name	Product Name	510(k) No.
Medical Device Technologies	En-Snare™ Endovascular Snare and Catheter	K021606

DESCRIPTION OF DEVICE:

The Fibrex™ Catheter Patency Device is a tri-axial delivery catheter assembly comprised of an outer catheter storing an inner guide structure and an inner stripping coil. The inner guide structure is for directing and guiding the stripping coil through the catheter to the free end of the catheter and back up around the exterior surface of the vascular catheter. The stripping coil is formed of a shape memory or super-elastic material, wherein the stripping coil is preformed to assume a helical shape wrapping about the outer surface of the vascular catheter in a manner providing for the stripping of build-up from the outer surface of the vascular catheter when the stripping coil is moved relative to the vascular catheter.

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The tri-axial delivery catheter assembly is attached to an injection molded plastic hand assembly that controls the movement of the guide catheter and subsequent insertion and rotation of the stripping coil. The delivery catheter assembly is adapted for selectively coupling to a luer connector secured to the venous lumen of a traditional vascular catheter.

The outer catheter of the Fibrex™ device is made from a biocompatible Polyimid/PTFE composite. The inner dual lumen tube is made from nylon. A Nitinol wire is housed in one lumen of the guide curve catheter to provide directional memory for the actuation and operation of the Nitinol stripping coil. Both the outer catheter and the guide catheter contain distal marking bands made from gold.

INDICATIONS FOR USE:

The Fibrex™ Catheter Patency Device is intended to disrupt fibrin sheath formation on both the external and internal surface of vascular access catheters, thus restoring functional patency.

FUNCTIONAL & SAFETY TESTING:

The Fibrex™ Catheter Patency Device was subjected to an animal study to evaluate the fibrin stripping capabilities of the device. It was also subjected to ring retention, and tensile tests. The results of the testing indicated that they are comparable to the predicate device.

TECHNICAL COMPARISON:

The following attributes of the Fibrex™ Catheter Patency Device were examined and found to be comparable to the predicate device:

1. Intended use
2. French Sizes
3. Length
4. Lumens
5. Distal end configuration
6. Intended anatomical location of distal end
7. Proximal end configuration
8. Materials
9. Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medical Device Technologies, Inc.
c/o Mr. Karl Swartz
Quality Assurance Manager
3600 SW 47th Avenue
Gainsville, FL 32608

Re: K040427
Fibrex™ Catheter Patency Device
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: February 19, 2004
Received: February 19, 2004

Dear Mr. Swartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K040427

510(k) Number (if known): K040427

Device Name: Fibrex™ Catheter Patency Device

Indications for Use:

The Fibrex™ Catheter Patency Device is intended to disrupt fibrin sheath formation on both the external and internal surface of vascular access catheters, thus restoring functional patency.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040427